FDA Inspection Readiness Guidance

Office of Clinical Trials Quality Assurance Program

UNC RESEARCH

Triggers for Inspections

Routine - submission of data to FDA in support of a Marketing Application or Amendment to an Existing Application

For Cause – investigate a specific problem that has come to FDAs attention

Subject or Sponsor Complaints

Report of UPIRSOs

Reports of Serious and/or Continuing Non-Compliance

Inspection Goal

Demonstrate that:

- Patient safety a priority
- Commitment to data integrity
- Compliance with regulations

INTERACTION GUIDELINES

- Be professional
- Ensure cell phones are on vibrate
- Answer questions honestly, factually, to the best of your knowledge
  - Avoid guessing/speculating answers – it is ok to say "I don't know the answer, but I will find someone who does"
  - Do not offer unsolicited comments – answer the question that is asked
  - Do not offer personal views or comments
  - Avoid generalities – e.g. "We typically do it this way" "It's usually done this way" "Generally, we….."

Interaction Guidelines

- Be comfortable with silence
- Do not argue with the Inspector – be respectful if there is a difference of opinion
- Do not place blame
- Do not refuse to provide requested documentation
- Do not refuse to allow the Inspector to speak with study team or those who were involved with the study
- Do not appear to be defensive
- Do not imply deficiencies are due to a lack of resources

Information the Inspector Will Request

- List of the PIs FDA regulated studies (usually going back 3-5 years)
  - IND/IDE #
  - Protocol #
  - Protocol Title
  - IRB #
  - Current Status
  - # of subjects enrolled

Additional information may be requested

During the Inspection

Be ready to provide information r/t:

- Adequate supervision of the study by the PI
- Informed consent process – who was involved, how was consent obtained, how was it documented
- Who performed various aspects of the protocol for the study
  - appropriate delegation of study procedures
  - study procedures, IP accountability, AE collection
  - data collection/entry
  - verification of I/E criteria
- Adherence to the protocol
  - deviations – who collected them, were they reported appropriately?
- Monitoring of the study

Opening Meeting

- PI (or designee) receives FDA form 482 – Notice of Inspection
- Introduction of Study Team/Attendees
  - Helpful to have business cards available to facilitate names/titles of attendees
- Ask what the inspection schedule will be - hours inspector plans to arrive/depart each day
- Review of general information r/t inspection
- Inspector may have some general questions
  - How many studies does the PI currently have? – includes enrolling/follow up
  - How many subjects were recruited/withdrawn/completed for those studies
- Begin review of documents associated with the study
  - Usually begins with regulatory documents then move to subject records
  - May compare data submitted to FDA with source

Daily Meetings

- Discussion of open items from previous day
- Review continues
- Requested Documents
  - Trend is now to provide documents on flash drive
  - Encryption
- End of day wrap-up meeting
  - Summarize any open items
  - Clarify any questions inspector may have that may lead to 483

Wrap-Up Meeting

- Discussion of observations found during the inspection
  - May only have some discussions points about best practices
  - FDA Form 483

Debrief

- If 483 issued – schedule debriefing meeting
  - Key study team members
    - Others to include:
      - OVCR
      - OHRE
      - IRB
      - OUC
      - OCT
      - Sponsor/CRO
- 15 days to respond
  - Support available from OVCR/OUC/OCT to assist with preparation of response